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June 19, 2007

**TO: Examiner Larry R. Helms  
and  
Examiner Alana M. Harris**

**GROUP: 1643**

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**SERIAL NO.: 09/810-385**

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(including this sheet)**

**MESSAGE:** Please provide a copy of the attached letter to Exrs. Helms and Harris.  
Thank you very much.

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= VIA FACSIMILE =

Larry R. Helms, Ph.D.  
Supervisory Patent Examiner  
U.S. Patent & Trademark Office  
Alexandria, VA 22313-1450Re: U.S. Application entitled "Compositions and Methods  
for Negative Regulation of TGF- $\beta$  Pathways"  
Serial No: 09/810,385 Filing Date: March 16, 2001  
Your Ref: PO1149US Job. No: L130 (PCT)  
Our Ref: WARF-0002

Dear Examiner Helms:

In follow up to our telephone discussion while Examiner Harris was on bereavement leave, a Notice of Appeal was filed to permit reconsideration of Examiner Harris' position concerning the sole remaining 112 issue. As discussed, Applicants have offered multiple, reasonable solutions which seem to have been either misunderstood or summarily dismissed. It would be greatly appreciated if you could review the case and advise if there is anything we can do to get the case allowed now.

As I explained, I believe that to maintain this rejection or force this case to appeal would be a great injustice to the University. A brief summary of the prosecution history follows for your assistance.

After filing multiple claim amendments, an affidavit by the inventor, and an RCE, the remaining issue is whether Applicant has met the written description requirement for the claimed assay. The basis of the instant invention is centered around Applicant's appreciation that Smad proteins, DNA-binding Smad co-repressor proteins and CtBP proteins interact to mediate repression of genes that are negatively regulated by TGF- $\beta$  signaling pathways. In this regard, the claimed assay employs a cell which co-expresses

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interacting proteins comprising a Smad protein, a DNA-binding Smad co-repressor protein and a CtBP protein and the use of a reporter with a wingless promoter to identify agents that directly interact with the Smad protein or the DNA-binding Smad co-repressor protein to prevent protein-protein or protein-DNA interactions required for repression of transcription from genes induced by TGF- $\beta$ , activin or bone morphogenetic protein signaling in cells.

In an effort to satisfy the written description requirement as to the method steps and reagents employed in the claimed assay, the original claims were amended to include a reporter and a Smad box-containing promoter. Having maintained the written description rejection, Applicant attempted to further clarify the nature of the promoter by subsequently amending the claims to recite a TGF-beta-dependent promoter. This clarification was also rejected and the claim was further amended to recite a promoter which is regulated by a TGF-beta, activin or bone morphogenetic protein signal. Because the Examiner maintained the written description rejection, Applicant made a further attempt to clarify by narrowing the scope of the claims to indicate that the promoter is a wingless promoter.

In the Advisory Action mailed May 31, 2007, the Examiner maintained the rejection, indicating that "a wingless promoter" has not been searched previously and is not of record in the specification.

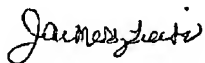
However, not only is a wingless promoter of record in the specification in paragraphs [0018] and [0023] and exemplified in Figure 6, the wingless promoter is also described as being a promoter which is regulated by the TGF-beta pathway (see paragraph [0005]). Therefore, being a species of the genus TGF-beta-dependent promoter or promoter which is regulated by a TGF-beta signal, a wingless promoter has already been searched. Moreover, because the wingless promoter is well-known in the art and has been employed in reporter protein-based assays, there is no question that the skilled artisan would readily know how to employ a wingless promoter in accordance with the instant assay. Therefore, written description requirement has been met.

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I would be happy to discuss via a telephone interview if you have any further questions, concerns or suggestions. To maintain this Final Rejection is not only fundamentally unfair, but clearly inconsistent with the legal requirements for patentability. Thank you for your consideration in this matter. It is greatly appreciated.

Best regards,

  
Jane Massey Licata

JML:por

cc: Examiner Alana M. Harris